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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/068,935	11/23/1998	DAVID PASCUAL	47714-5004	2851

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EXAMINER
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GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/31/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/068935	Applicant(s) PASCUS	
	Examiner Gambro	Art Unit 1644	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.

2a) ☒ This action is FINAL.      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) \_\_\_\_\_ is/are pending in the application. 55-113

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 60, 61, 65, 66, 69-71, 73-75, 77-79, 81, 82, 84, 85, 88, 91-92, 107, 108, 119, 111

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) \_\_\_\_\_ is/are rejected. 55-59, 61-64, 67, 68, 72, 76, 80, 83, 86, 87, 90, 98-106

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to. 109, 112, 113

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 8/14/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. The request filed 4/28/98 (Paper No. 10) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/068,935 is acceptable and a CPA has been established. An Office Action on the CPA follows.

Applicant's amendment, filed 4/30/03 (Paper No. 27), has been entered.

The numbering of claims is not in accordance with 37 C.F.R. 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 CFR 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 112 has been renumbered 114.

Claim 114 has been added.

As pointed out previously, applicant's election of attachment molecules comprising proteins and glycoproteins, endothelial cells, mannose, selectin or integrin, ICAM-1 and Candida in Paper No. 17 has been acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse).

According to applicant, claims 55-90 and 95-111 corresponded to the elected Group I.  
See page 16 of applicant's election, filed 5/17/01 (Paper No. 17).

However as pointed out previously, claims 95-97 read on kits comprising antibodies and not pathogen adhesins. Antibodies and pathogen adhesins differ in structure, physicochemical properties and modes of actions and are considered distinct.

As pointed out in the previous Office Action (Paper No. 20), it appears that claims 55-59, 62-64, 67, 68, 72, 76, 80, 83, 86, 87, 89, 90, 98-106 and 109 read on the elected invention attachment molecules comprising proteins and glycoproteins, endothelial cells, mannose, selectin or integrin, ICAM-1 and Candida.

Claims 55-59, 62-64, 67, 68, 72, 76, 80, 83, 86, 87, 89, 90, 98-106, 109, 112-113 and newly added claim 114 are being acted upon as the elected invention.

Claims 60, 61, 65, 66, 69-71, 73-75, 77-79, 81, 82, 84, 85, 88, 91-97, 107, 108, 110 and 111 have been withdrawn from consideration as being directed to a non-elected invention/species. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

Claims 1-54 have been canceled previously.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. This Office Action will be in response to applicant's arguments, filed 4/30/03 (Paper No. 27). The rejections of record can be found in the previous Office Actions (Paper Nos. 20/24).

3. In view of the papers filed 4/30/03 (Paper No. 1.48), it has been found that this application, as filed, through error and without any deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 C.F.R. § 1.48.

The inventorship of this application has been changed by removing Clifford Bond and Gordon McFeters, James Burritt and Don Burgess as inventors.

The instant inventors are David Pascual, Pati Glee, John Jutila, Mark Jutila, Robert Bargatze, Barry Pyle, Jim Cutler and Yongmoon Han.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 55-59, 62-64, 67, 68, 72, 76, 80, 83, 86, 87, 89, 90, 98-106, 109, 112-113 and newly added claim 114 are rejected under 35 U.S.C. § 102(e) as being anticipated by Cutler et al. (U.S. Patent No. 5,578,309) alone as well as acknowledged by applicant's disclosure on page 2, paragraphs 1-2 of the specification as set forth in the previous Office Actions (Paper Nos. 20/24).

Applicant's arguments, filed 4/30/03 (Paper No. 26), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant asserts that the '309 patent does not disclose the genus covered by the pending claims and that the species taught by the reference does claimed genera obvious because there is no disclosure of the general concept, i.e., that isolated pathogen adhesin molecules that bind to a host cell or extracellular matrix under shear conditions are particularly useful in a vaccine, or a diagnostic assay kit or composition or a therapeutic composition.

Applicant asserts that Han and Cutler are the inventors of the common material and therefore the priority claim to the '309 patent is proper and that the more general concept was invented by other inventors in addition to Han and Cutler.

Applicant asserts that the '309 patent does not teach a pathogen adhesin molecule that functionally mimics a ligand for a host cell molecule, such as a selectin or integrin, nor a number of the claimed limitations.

It is noted that applicant's previous rebuttal, filed 8/12/02 (Paper No. 21), relied simply on the assertion of claiming priority and not whether the prior art taught the claimed invention.

Applicant has submitted that the specification of the instant application has been amended to indicate that the present application is a continuation-in-part of the application that issued as U.S. Patent No. 5,578,039 and, in turn, the '309 patent cannot be cited as art against the present application.

As pointed out previously in contrast to applicant's assertions, U.S. Patent No. 5,578,309 is "by another" (See MPEP 2136.04) and the priority date of the instant claims, based upon written description, does not precede the priority 102(e) date of U.S. Patent No. 5,578,309. Therefore, U.S. Patent No. 5,578,309 stands as prior art.

Therefore, the record indicates that applicant has acknowledged that the prior art taught the claimed invention, namely the elected invention as it reads simply read on well known vaccine formulations of a broad spectrum of pathogens (i.e. *Candida albicans*) at the time the invention was made.

As indicated previously, Cutler et al. teach *Candida albicans* vaccines (see entire document, including Background of the Invention, Summary of the Invention, Detailed Description of the Invention and Claims. Therefore, Cutler et al. teach *Candida albicans* vaccine that anticipate the claimed and elected invention. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations encompassing the elected invention of attachment molecules comprising proteins and glycoproteins, endothelial cells, mannose, selectin or integrin, ICAM-1 and *Candida* as well as the claimed characteristics (e.g. specificity, shear conditions, would be inherent properties of the referenced *Candida albicans* vaccines.

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Also, see Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999) and Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); For example in Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); the following was noted. "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Page 2, paragraphs 1-2 of the specification acknowledges that the disclosure of Cutler et al. In USSN 08/483,558, now U.S. Patent No. 5,578,309 discloses vaccines for the treatment of *Candida albicans* comprising adhesion molecules but "did not recognize that pathogens and infectious agents use the host cell's own machinery to mimic the host and enter cell and tissue with relative ease".

Again, the claimed functional limitations would be inherent properties of the referenced *Candida albicans* vaccines. If the claimed products, including vaccines merely comprises a known composition (*Candida albicans* adhesins), the claimed product carries little weight absent evidence of structural difference. Applicant has not shown any structural difference between the prior art the claimed invention. The record shows that applicant's previous response in conjunction with the disclosure of the specification as filed acknowledges the prior art meets the claimed invention.

Applicant has not distinguished the structure of the prior art *Candida albicans* vaccine formulations, which include adhesins from *Candida albicans* (e.g. Examples 1-3, 17), liposomes (e.g. Examples 4-5, 10, 17-25), conjugates such as those suitable for human use (Examples 26-27). Newly added claim 114 is anticipated by the prior art *Candida albicans* vaccines, including Examples which were shown to vaccinate mucosally with *Candida albicans* (See Examples 22 and 24).

A species will anticipate a claim to a genus. See MPEP 2131.02.

Applicant's arguments are not found persuasive.


6. No claim allowed.

7. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

  
Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
July 10, 2003